

Message Text

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PAGE 01 STATE 095099
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-06 /022 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:PFF
APPROVED BY OES/APT/BMP: JFRY
DHEW/OIH:BHOLLAND
EA/J:DFSMITH(INFO)

-----272316Z 019686 /61

P 272207Z APR 77
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 095099

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, JA

SUBJECT: DIAGNOSTIC PRODUCT DEVIATING FROM STANDARD
(RECALL T-081-7)

FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: HAEM-C BLOOD REFERENCE AND CONTROL,
NORMAL. PRODUCT IS PACKAGED AS HAEM-C NORMAL WITH 6/7 ML.
VIALS OF NORMAL OR IN A DUOPAK WHICH CONTAINS 2/7 ML. VIALS
OF HAEM-C NORMAL AND 2/7 ML. VIALS OF HAEM-C ABNORMAL.
PRODUCT NUMBER FOR NORMAL Y230. PRODUCT NUMBER FOR
DUOPAK Y223.

PRODUCT IDENTIFICATION: PRODUCT LABELED HAEM-C NORMAL
BLOOD REFERENCE AND CONTROL FOR HEMATOLOGY, FOR IN-VITRO
DIAGNOSTIC USE 7 ML. VIALS J.T. BAKER DIAGNOSTICS BRAND.

MANUFACTURER/RECALLING FIRM:

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J.T. BAKER DIAGNOSTICS
DIVISION OF J.T. BAKER CHEMICAL CO.
2266 AVENUE A
BETHLEHEM, PA. 18017

REASON FOR RECALL: DURING ROUTINE IN-HOUSE TESTING IT WAS
NOTED THAT TWO (2) LOTS OF MATERIAL CONTAINING SIMULATED

WHITE BLOOD CELLS GAVE SPURIOUS RESULTS WITH EXCESSIVE MIXING OF THE PRODUCT. VALUES DROPPED FOR THE WHITE BLOOD CELLS AND INCREASED FOR THE MEAN CORPUSCULAR VOLUME. BECAUSE OF THESE FINDINGS THE FIRM REQUESTED DISCONTINUANCE OF THE PRODUCT WITH THE FOLLOWING LOT NUMBERS:

PRODUCT NUMBER	PACKAGE LOT NUMBER	HAEM-C NORMAL LOT/NUMBER
Y230	7003L	7003L
#Y233	7033C	7018J
#Y233	7024G	7003L

THE HAEM-C ABNORMAL CONTAINED IN THIS PACKAGE IS SUITABLE FOR USE. FIRM INDICATES IT WILL REPLACE HAEM-C NORMAL AT NO CHARGE.

POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF THEY HAVE BEEN ALERTED REGARDING PROBLEM BY TWX/LETTER DATED FEBRUARY 10, 1977.

FOREIGN CONSIGNEE:

TOAGOSEI CHEMICAL INDUSTRIAL CO.
14-1 NISHI SHIMBASHI
1-CHONE, MINATO-KU
TOKYO 105, JAPAN
ATTN: HEMATOLOGY SUPERVISOR

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 27-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE095099
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:PFF
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770147-0824
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770412/aaaaakhx.tel
Line Count: 99
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 743e3e9c-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 07-Feb-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2675004
Secure: OPEN
Status: NATIVE
Subject: DIAGNOSTIC PRODUCT DEVIATING FROM STANDARD (RECALL T-081-7) FDA ADVISES OF THE FOLLOWING RECALL
TAGS: OGEN, ETRD, EIND, TBIO, JA
To: TOKYO
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/743e3e9c-c288-dd11-92da-001cc4696bcc
Review Markings:
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